Genentech, Inc.

FACSIMILE TRANSMITTAL

1 DNA WAY South San Francisco, CA 94080 (650) 225-1000

Facsimile: (650) 952-9881

DATE: April 12, 2005

Please deliver the following page(s) to:

NAME: Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Fax No.: (703) 872-9306

FROM: Wendy Lee UM

Registration No.: 40,378

RE:

U.S. Serial No.: 09/602,812

Our Docket No.: P1467R2

Number of Pages including this cover sheet -

ERTIFICAT	TON OF	FACSI	MILE .	TRANSMISSION
	INTRE	37 CE	267	•

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Anna Kan

Type or print name of person signing certification

CONFIDENTIAL NOTE

The documents accompanying this facsimile transmission contain information from GENENTECH, INC, which is confidential or privileged. The information is intended only for the individual or entity named on this transmission sheet. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this faxed information is strictly prohibited. If you have received this facsimile in error, please notify us by telephone immediately so that we can arrange for the return of the original documents to us and the retransmission of them to the intended recipient.

If you do not receive all pages, please notify Anna Kan at (650) 225-2830.

Enclosed for consideration and entry on the record in connection with the above application are: this cover page, APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b) (dup), PETITION UNDER 37 C.F.R. § 1.183 (dup), Printout of PTA provided on PAIR, 4/28/2003 IDS with 1449 Form and return postcard, 4/28/2003 1449 Form intialed by the Examiner 11/19/2003 and Fees \$200 and \$400.

Patent Docket P1467R2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Camellia W. Adams et al.

Serial No.: 09/602,812

Filed: June 23, 2000

For:

Humanized Anti-ErbB2 Antibodies and

Treatment with Anti-ErbB2 Antibodies

Group Art Unit: 1642

Examiner: Anne Holleran

Confirmation No: 9612

CUSTOMER NO: 09157

Certificate of Facainale Transmission Under 37 CFR § 1.8

In accordance with CFR § 1.6(d), this correspondence addressed to Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 is being transmirred to facsimile No. (703) 872-

April 12, 2005

Anna Kan

PETITION UNDER 37 C.F.R. § 1.183

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Şir:

Applicant petitions the Director for waiver of the requirement of 37 C.F.R. § 1.705(b) that an application for patent term adjustment be filed no later than the date that the issue fee is paid. An application under § 1.705(b) is filed concurrently with this petition.

The Director is authorized and requested to debit our Deposit Account No. 07-0630 the amount of \$400 in payment of the fee required under § 1.17(f) for consideration of this petition. Any other fees as may be required in connection with this petition or the concurrently filed application under § 1.705(b) may also be debited, and any overpayment credited, to the same account.

Facts

- 1. This patent application was filed on 23 June 2000. A Notice of Allowance was mailed on 12 January 2005, setting a three-month due date for payment of the issue fee. Thus, the issue fee was due on 12 April 2005.
- 2. The Notice of Allowance was accompanied by a Determination of Parent Term Adjustment (PTA) under 35 U.S.C. § 154(b) indicating that the application was eligible for PTA of 0 days.



Patent Docket P1467R2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Camellia W. Adams et al.

Serial No.: 09/602,812

Filed: June 23, 2000

For: Humanized Anti-ErbB2 Antibodies and

Treatment with Anti-ErbB2 Antibodies

Group Art Unit: 1642

Examiner: Anne Holleran

Confirmation No: 9612

CUSTOMER NO: 09157

Certificate of Facalmile Transmission Under 37 CFR § 1.8

In accordance with CFR § 1.6(d), this correspondence addressed to Contributioner for Patenta, P.O. Box 1450 Alexandria, VA 22313-1450 is being transmitted to facsimile No. (703) \$72-9306

PETITION UNDER 37 C.F.R. § 1.183

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant petitions the Director for waiver of the requirement of 37 C.F.R. § 1.705(b) that an application for patent term adjustment be filed no later than the date that the issue fee is paid. An application under § 1.705(b) is filed concurrently with this petition.

The Director is authorized and requested to debit our Deposit Account No. 07-0630 the amount of \$400 in payment of the fee required under § 1.17(f) for consideration of this petition. Any other fees as may be required in connection with this petition or the concurrently filed application under § 1.705(b) may also be debited, and any overpayment credited, to the same account.

Facts

- This patent application was filed on 23 June 2000. A Notice of Allowance was mailed on 12 January 2005, setting a three-month due date for payment of the issue fee. Thus, the issue fee was due on 12 April 2005.
- The Notice of Allowance was accompanied by a Determination of Patent Term Adjustment 2. (PTA) under 35 U.S.C. § 154(b) indicating that the application was eligible for PTA of 0 days.

Serial No.: 09/602,812

- 3. Shortly after receiving the Notice of Allowance, applicant's undersigned agent asked outside counsel to review the Office's determination of PTA in this application. As of Friday last week (8 April 2005), outside counsel had not completed that review.
- 4. Applicant's agent was concerned that because of travel and meetings scheduled in the first part of the week of 11 April, it might be difficult to file the payment of the issue fee during that time and by the 3-month due date. Believing in error that the Rules permitted the submission of an application for patent term adjustment after the payment of the issue fee, applicant's agent paid the issue fee on 8 April 2005 by a fax submission authorizing an appropriate debit from applicant's Deposit Account.
- Outside counsel completed its review of the Office's determination of PTA on Monday 11 April and communicated its findings to applicant's agent. Counsel also advised that 37 C.F.R. § 1.705(b) does in fact require that an application for patent term adjustment be filed no later than the payment of the issue fee.
- 6. Applicant believes that the Office's calculation of PTA is in error. In particular, as set forth in detail in the application under 37 C.F.R. § 1.705(b) filed concurrently with this petition, applicant believes that the correct period of PTA is 329 days plus the number of days from the date of the Notice of Allowance until the date that a patent is granted, not 0 days as determined by the Office.
- 7. Applicant's application under § 1.705(b) and this petition are filed on 12 April 2005. This date is three months after the date that the Notice of Allowance was mailed (i.e., on the date that the issue fee was originally due).
- 8. The error of failing to submit an application for patent term adjustment before or on the same day as the payment of the issue fee occurred without deceptive intent on the part of applicant's agent or outside counsel.

Discussion

37 C.F.R. § 1.705(b) requires that an application for review of a reduction in PTA under § 1.704 be filed no later than the payment of the issue fee. This requirement is not mandated by statute. The authorizing legislation, the Patent Term Guarantee Act of 1999, Pub.L. 106-113, sec. 1000(a)(9), 113 Stat. 1501A-557 (\$. 1948 § 4402(a)) (29 Nov. 1999), codified at 35 U.S.C. § 154(b), provides only that "the Director shall — ... provide the applicant one opportunity to request reconsideration of any patent

Serial No.: 09/602,812

term adjustment determination made by the Director." § 154(b)(2)(B)(ii). Thus, the Director has the authority to waive the timing requirement of 37 C.F.R. § 1.705(b).

The requirement for filing an application for patent term adjustment no later than the payment of the issue fee was implemented to promote the administrative efficiency of the Office. See M.P.E.P. § 2734 (Office requires timely submission of applications for patent term adjustment so that "the issuance of the patent will [not] be further delayed by a protracted patent term adjustment determination proceeding"). Applicant acknowledges that the filing of its application after the issue fee has been paid will disrupt the normal flow of pre-issue processing in this application to some extent. Applicant believes, however, that such disruption will be minimal in this instance, inasmuch as the issue fee was paid only two business days ago.

This minimal delay should not materially impair the ability of the Office to prepare this application for grant within the normal post-allowance timeframe. In this connection, applicant observes that the concurrently filed application under § 1.705(b) will be received by the Office on the same day that it would have been received if applicant had tendered a timely payment of the issue fee on the due date set in the Notice of Allowance. In any event, applicant agrees that any delay in the grant of a patent that results from consideration of this petition and the late filing of its application under § 1.705(b) should be treated as a circumstance that leads to a reduction of PTA under § 1.704.

There is also an element of fairness in requiring every applicant to request reconsideration of PTA within the same timeframe. In this case, applicant is asking the Office to accept its application under § 1.705(b) within the same time period (i.e., within three months of the mailing of a Notice of Allowance) as is ordinarily provided by the Rules. Thus, granting this petition will not inappropriately confer a benefit on applicant with respect to the interval allowed for reviewing the Office's determination of PTA that is not afforded to all applicants as a matter of course.

Finally, on the present facts, justice requires that the timing requirement of § 1.705(b) be waived as requested. The Patent Term Guarantee Act of 1999 is fundamentally remedial in nature. The legislation "goes most of the way in reversing the 1994 patent term reduction by extending patent term completely to compensate for delays in the processing of the Patent and Trademark Office or any other delay resulting from actions taken by anyone else other than the patent applicant." As set forth in the concurrently filed application under § 1.705(b), the net "delays in [PTO] processing" for which applicant

Floor remarks of Rep. Rohrabacher, 106 Congr. Rec. H6943 (3 August 1999).

Serial No.: 09/602,812

should be compensated will amount to approximately one year by the time a patent is granted. Depriving applicant of this compensatory patent term would be an unreasonably harsh result of strict adherence to the Rules and would trustrate the remedial purpose of the Act. This is particularly so interaction as applicant's error involves filling its application under § 1.705(b) only two business days late (or more precisely, paying the issue fee two business days early). Accordingly, applicant believes that it is appropriate for the Director to exercise his discretion to suspend the timing requirement of the rule to give full and fair effect to the Patent Term Guarantee Act as to this application.

Conclusion

Applicant submits that this situation is extraordinary within the meaning of § 1.183. Applicant requests that the Director waive the requirement of § 1.705(b) for submission of an application for patent term adjustment no later than the payment of the issue fee, and that the concurrently filed application under § 1.705(b) be accepted as timely.

Respectfully submitted,

GENENTECH, INC.

Date: April 12, 2005

Wendy Lee

Reg. No. 40,378

Telephone No. (650) 225-1994